Dockets Management Branch, Docket # 1354
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1051 (HFA-305)
Rockville, MD 20852

RE: Public comment and suggestions regarding Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses

Dear Center for Devices and Radiological Health,

In light of serious health concerns for women who have compromised immune systems after breast cancer, women who previously had ruptured or failed implants and now have high levels of silicone and secondary potentially toxic chemicals in their bodies, and young women of childbearing age who are choosing to be implanted without knowing what the long-term outcome might be to their health of that of their future children, our national non-profit network of support organizations believe the FDA regulation of saline breast implants with a silicone shell must include strong safeguards to protect a womans health and that of our future generations. Recent research on autoantibody production includes: A Comparison of Autoantibody Production in Asymptomatic and Symptomatic Women with Silicone Breast Implants , Zandman-Goddard, G., et al, J Rheurnatol 1999; 26:73-7, Influence of Long Term Silicone Implantation of type II Collagen Induced Arthritis in Mice, Schaefer, C.J. , et al, Ann of Rheu Disease, August 1999; 58:503-509, and Immunological Resnonses to Silicone Breast Implants FDA OST Annual Report 1998. Also please refer to the FDA's Scleroderma Court Study on high incidence of this rare disease in breast implanted women, Dr. Lori Brown's FDA rupture study, and Dr. Louise Brinton's NCI data on adverse effects.

Therefore, our groups find the wording unacceptable as stated in the proposed draft in light of our many health concerns. The use of the word "**should**" leaves the possibility for non-compliance and misinterpretation. We request the wording **be** changed to **must** in certain vital circumstances. For example please consider the following:

Page 5 under Manufacturing/Sterilization, line 32, sentence should read " **For Et0 sterilization, the sponsor must provide the maximum residual levels for ethylene oxide, ethylene chlorohydrin and ethylene glycol met and a rational why the residual levels are acceptable."**

Published research by Epstein (1995) states "A 1988 FDA audit of Cooper Surgical revealed a wide range of deficiencies in control procedures (FDA, 1988). These included the absence of validated and formalized procedures for methods for sterilization and aeration, the absence of established residue limits, and failure to test for residues of ETO. Such concerns are prticularly significant because these residues - ranging up to 443 mg/kg (ppm) - are known to persist on medical products, including plastics, even

after seven days areation (IARC 1985; WHO 1985; U.S. EPA 1985). FDA tolerances for implants are 250 ppm (IARC 1985). Other products are also known to retain measureable levels of ETA several months after fumigation (ATSDR 1990)."

Page 6 under General Information, line 7, sentence should read **"A complete list of all of the chemicals used in the manufacture of the breast prosthesis must be provided."**

For patients to have true informed consent, they must be provided information on all chemicals contained in any device implanted in their body. Chemicals that last for a long period of time and cannot be excreted readily should be identified. All ingredients must be listed in all foods and all drugs. The standard should not be less in devices.

Page 6, line 11, sentence should read **"Material safety data sheets (MSDS) must be provided for each chemical."**

Potential toxicity or adverse effects must be provided in informed consent to patient.

Page 6, line 14, sentence should read **"Chemical analyses of the elastomer shell, including the patch and valve, must be provided."**

The IOM report on the Safety of Silicone Breast Implants (July 1999) reports tin has been added to Mentor and McGhan saline implant shells. They state "Human data for organotins are sparse to nonexistent..."

Page 6, line 21, sentence should read **"The identification of releasable chemicals must be provided to identify potentially toxic chemicals and estimate the upper limits of the chemicals that could be released to the patient."**

For patients to have true informed consent, they must know the amounts of potential toxic chemicals they may be placing in their body.

Page 6, line 38, sentence should read **"Extracts that may contain oligomeric or polymeric species must have the molecular weight distribution provided, along with the number and weight average molecular weights and the polydispersity. Experimental evidence must be provided to show that exhaustive extraction has been achieved with one of the solvents."**

Baylor College of Medicine research documents siloxane oligomers as toxic and fatal to mice. An injection of approximately 0.2ml (about 4% of a teaspoon) killed 50% of the mice in seven days after injection Cyclosiloxanes Produce Fatal Liver and Lung Damage in Mice, Lieberman, MW, et al, Environ Health Perspect 107: 161- 165 1999.

Page 6 last sentence should read **"The percent recovery, especially for the polydimethylsiloxanes (D3 or D4), must be reported."**

Both D4 and Polydimethylsiloxanes (PDMS 10cs) are on a high priority testing list at the EPA. This testing is being done voluntarily by Dow Corning and is to include chronic toxicity, reproductive/fertility/developmental toxicity with neurotoxicity

assessment and immunotoxicity (Memorandum of Understanding, Dow Corning and EPA, April 9, 1996). A 1975 Dow experiment demostrated that D4 had both a very strong immunostimulatory and cytotoxic action The IOM report states regarding D4 and D5 "There are few chronic lifetime or carcinogenesis studies (less than 3%) and few immunological studies (less than 5%)."

Page 7, line 2, should read **"All chemicals below a molecular weight of 1500 must be quantified and identified after exhaustive extraction of the final sterilized device. These include, but are not limited to, residual monomers, cyclics, and oligomers; known toxic residues such as polychlorinated biphenyls (PCBs) if dichlorobenzoyl peroxides are used, aromatic amines, if polyurethanes are used, and heavy metals and residue catalysts. If the heaw metal platinum is used it must be stated if it is in the zero valence form in the final cured state or whether it is in a reactive valence state. Residues of ethylene oxide and ethylene chlorohydrin must be reported if ethylene oxide is used for sterilization, as well as additives and adjuvants used in the manufacture of the device, such as plasticizers, antioxidants, etc.**

The IOM report states 'Platinum can produce chemical pneumonitis...platinum in its multivalent state has immunogenic potential." Release of Low Molecular Weight Silicones and platinum from Silicone Breast Implants, Lykissa, E.D., et al, Analytical Chem, Vol 69;23 1 0/1/97 documents platinum leaking through intact implants. Dr. Michael Harbut concludes breast implants contain 500 to 1500 times the Federal standard of safe levels of platinum salts allowed Asthma in Patients with Silicone Breast Implants: Report of a Case Series and Identification of Hexachloraplatinate Contaminate as a Possible Etiologic Agent, IJOH 1999; 3:73-82. Dr. Arthur Ericsson, Board Certified Neurologist, concludes "Over 87% of symptomatic patients appear to have a neuropathy (demyelinating and axonal - diagnosis made on nerve and muscle biopsy and ELISA analysis)...22-25% have evidence of autoimmune thyroid disease... 10- 12% have evidence of central demyelination" Syndromes Associated with Silicone Breast Implants 'linical Studv and Review, J Nutritional & Env Medicine (1998) 8; 35-5 1. Is it possible that silicone when combined with platinum acts as a lipid soluble neuro-toxin?

Page 7, line 21, sentence should read **"The requirements for the analysis of the gel are very similar to those for the elastomer shell. A detailed chemical analysis of the gel product must be provided, including both qualitative and quantitative analyses for volatiles, heavy metal contents, and extractables such as cyclic polysiloxanes. This information must include the identification of the polymers present, molecular weight averages and polydispersities of the polymers, and the identification and quantification of all compounds present with a molecular weight of 1500 or less."**

Low Molecular Weight Silicones Are Widely Distributed after a Single Subcutaneous

Injection in Mice, Kala, S.V., et al, Am J of Path, 152;3 Mar 1998 documents silicones in ten different organs including the highest concentration in the brain lymph nodes, lungs, reproductive organs, and can persist over an extended period of time.

Page 8, line 28 should read **"Because data show that several types of bacteria (particularly gram-negative species) and fungi can grow and reproduce in a restricted saline environment for extended periods of time and permeate or bleed through an intact shell. FDA believes that the bleed rate for saline-filled implants must be determined."**

Microbial Growth Inside Saline-Filled Breast Implants, Young, V.L., et al, Plas and Recon Surgery, July 1997 states contaminated implants could cause significant health risk should micro-organisms be introduced into a patient at the time of implant rupture or deflation or should organisms migrate through a filler valve or implant shell.

Page 8, line 30, sentence should read **"Because gel or fluid can permeate or bleed through an intact shell, FDA believes that the bleed rate of a silicone gel-filled or of an alternative filler device must be determined."**

Because gel or other toxic fluids has been documented to spread to all parts of the body, the rate becomes important information to determine risk.

Page 9, line 17, should read **"The testing must address the possibility that compounds or degredation products of the filler will diffuse out of the implant, changing the composition of the filler and perhaps the performance of the implant over time. The toxicology of the filler and degradation products must be tested and described below. The simultaneous rupture of two implants must not deliver a toxic dose to the body.**

Toxic Shock Syndrome becomes a major concern with the simultaneous rupture of two implants if filled with saline contaminated with bacteria or fungus.

Page 9, line 24, sentence should read **" The level of potential local and systemic toxicity of any substance introduced into the body by the breast implant must be assessed."**

The IOM report states "Historically, silicone toxicology has tended to focus on short term acute and subacute studies and has suffered from a proportionate dearth of chronic, lifetime, and immunologic studies...some silicones have clear biological effects. None can be said to be inert, if this implies an absence of tissue reaction."

Page 9, line 35, sentence should read **"Chemicals without adequate safety data in the literature must initially be based on the worst case levels of toxicants that would result if all the leachable components were released from the implant to the body at once."**

The IOM report states "It seems reasonable to conclude that both the physical and

the chemical characteristics of implants should be spelled out clearly in product changes, introductions, and investigations because they may influence patient reactions and patient health."

Page 10, line 1, sentence should read **"The toxicity assessment must initially be based on the worst case levels of toxicants that would result if all the leachable components were released from the implant to the body at once."**

With a documented 70% failure rate on gel-filled breast implants and no way to remove the gel after it leaks or spreads to all parts of the body, this information becomes vital in determining risk. Because a gel-filled rupture may be silent, a woman has no way to protect herself or end the experiment.

Page 10, line 15, sentence should read **"For known toxic compounds, e.g., the low molecular weight siloxanes contained in silicone implants, well-supported estimates of the maximal serum concentration and tissue accumulation levels must be estimated to determine if the compounds will produce significant adverse effects."**

The recently published research Quantitative Detection of Silicone in Skin by means of Electron Spectroscopy for Chemical Analysis (ESCA), Haycox, C.L., et al, J of the American Academy of Dermatology, May 1999 documents the ability to quantify the amount of silicone in skin and document adverse effects.

Page 10, line 37, sentence should read **"Reproductive and teratogenicity studies must measure rates of conception as well as record the number of fetal deaths and malformations. The studies must include two generations."**

The IOM report states "Whether silicone passes the placenta has not been evaluated in women.. ." After thirty years of use in women of childbearing age, this is unconscionable and irresponsible not to have this information in light of suspected endocrine disruption capabilities of silicone and effects on the uterine wall.

Page 11, line 9, sentence should read **"Therefore, adequate long-term studies with implantation of device materials must be conducted to evaluate the long-term toxic and carcinogenic potential. Complete reports from the genotoxicity testing must be provided."**

In 1988 a senior staff scientist on the FDA Task Force reviewing carcinogenicity data (Public Citizen 1988) urged that a medical alert be issued to warn the public of the possibility of malignancy development in humans following long-term implantation of silicone breast protheses. Recent published research (August 1999) by Schaefer documents the development of foreign body sarcomas in mice implanted with silicone elastomers only, after long term exposure. Our groups believe the present epidemiological studies are flawed and inconclusive. Concerns remain regarding multiple myeloma, lung, and vulva cancer as well as what effect the reduction in Natural Killer cell counts

after exposure to silicone gel will have in controlling cancerous tumor cell growth.

Page 11, line 12, sentence should read **"The testing must, at minimum, consist of bacterial mutagenicity (including point and frame shift mutations) and a mammalian cell forward mutation assay. Mammalian cells must also be tested for cell transformation and for genetic damage in tests such as unscheduled DNA synthesis, sister chromatid exchange, or chromosome aberration assays."**

The FDA's OST study documents using two different assays, autoantibodies to connective tissue proteins and to DNA in women with silicone breast implants. Concerns remain regarding potential DNA damage from silicone or its components or from the autoantibodies they produce.

Page 12, line 15, sentence should read **"The testing must be performed on material taken from the thinnest location of the prosthesis shell."**

Page 12, line 21, sentence should read **"The testing must be performed on material specimens taken from the thinnest location of the prothesis shell."**

Page 12, line 26, sentence should read **"Each type of patch/shell joint and valve/shell joint must be tested."**

Page 12, line 28, sentence should read **"However, unlike ASTM F703, destructive testing must be conducted (i.e. test sample to failure). The force of failure must be reported."**

In light of high failure rates of 70% reported in the published research Silicone Gel Breast Implant Failure and Frequency of Additional Surgeries: Analysis of 35 Studies Report of More Than 8,000 Explants, Marotta, J Biomed Mater Res, 48;354-364, 1999, this becomes vital information to determine risk.

Page 12, line 35, sentence should read **"There is no existing standard methodology to address fold flaw, so a sponsor must provide a test method with an adequate rationale."**

FDA's OST research The Effect of Fold Flaws on Rreast Implant Shells Failure Characteristics indicate that fold flaws reduce the life expectancy of an implant which subjects patients to additional surgery and increases risk.

Page 13, line 4, sentence should read **"If the sponsor chooses to perform testing that addresses both of these issues together, then the quantity and particle size distribution of the abraded material must be provided, with particular focus on the percentage of particles less than 100 micrometers, including photomicrographic documentation of the particles present in the debris field."**

FDA's OST research documents polymer-on-polymer abrasion and resulting debris

which raises many health concerns.

Page 13, line 29, sentence should read **"Static rupture testing must be performed to capture the compressive static force required to rupture** a **total finished, sterilized device."**

Page 14, line 14, sentence should read **"Valve competence tests conducted on saline-filled breast prosthese must demonstrate the resealing capabilities of the valve."**

Page 14, line 17, sentence should read **"The maximum expected pressures exerted on the device during typical service loading must be defined, and the devices must be tested in a pressure regime that allows for a margin of safety."**

Page 14, line 24, sentence should read **"Therefore, the sponsor must predefine a pressure that adequately define *in vivo* conditions, with a rationale, and provide testing at that pressure. Thus, sponsors must demonstrate that valve integrity is maintained at actual anticipated maximum *in vivo* loads, well in excess of those stipulated by the F703 standard."**

Page 14, line 31, sentence should read **"In addition, valve integrity testinp must be performed on devices that were used in the fatigue testing described in section 3.8 above."**

Page 14, line 36, sentence should read **"Cohesivity testing must be performed to measure both the rheological (flow) properites and the integrity (connectivity) of the gel. Testing must be conducted on gel-fill material obtained from finished, sterilized devices."**

Page 15, line 5, sentence should read **"FDA believes that a PMA may be filed with a minimum of 3 years of patient follow-up on a sufficient cohort of patients to evaluate the effectiveness of the product. This is based on additional post-PMA filing follow-up for a total of a minimum of 30 years of prospective patient experience to determine safetv. Sample size estimates must be based on the precision of safety and effectiveness outcomes or detecting** a **clinically meaningful difference at three years but with consideration to lost-to follow-up rates estimated for 30 years of patient follow-up."**

With a long latency suspected for carcinogenicity , connective tissue, neurological disorders, Natural Killer Cell counts to decline, and autoantibodies to appear, a thirty year patient follow-up seems reasonable.

Page 15, line 13, should read **"Studies must include the separate patient cohorts of primary augmentation, urimarv reconstruction, and/or revision."**

Page 15, line 27, should read **"For patients who undergo removal without replacement or removal with replacemnt with another manufacturer's implant, then the FDA requires manufacturer or replacement manufacturer to continue follow-up evaluation."**

The IOM report recommends ongoing surveillance of recipients of silicone breast implants including long-term outcomes and local complications. The patient who has her implants removed may be experiencing adverse health effects and should be monitored and included in data on long term outcomes.

Page 17, line 10, should read **"Rates and time course evaluations for the following must be provided, regardless of the device relatedness of the event."**

Page 17, line 3 1, should read **"m. any other device malfunction or adverse health event (including any effects of the immune system, and the reproductive svstem, neurological disorders including cognitive dysfunction, and cancer). If anv of the above complications or adverse events occur. FDA reauires the plastic surgeon or treating physician to fill out a Medwatch form within a sixtv dav period of onset if the adverse event results in death, life threatening event. disabilitv, hospitalization (initial or prolonged including over-nbht stavs at elastic surgeon facilities). congenital anomaly, required intervention to prevent permanent impairment or damage (to include explantation) and other significant adverse effects.**

Page 18, line 30, should read **"This evaluation must be conducted on all patients yearly, with follow up by a rheumatologist or other appropriate specialist, if indicated, and with collection of serological information (e.g., ANA, RF, ESR, immunoglobulin level, CPK, SPEP, complement levels, Natural Killer cell counts, etc.) if indicated."**

The IOM report states "Consistent with animal toxicology studies noted earlier, it appears the Natural Killer (NK-cell) counts in humans might be affected by exposure to silicone gel." Removal of silicone breast implants was followed by an increase in NK-cell function in 60% of women studied by Campbell suggesting a direct causal relationship. Natural killer cells, a cornerstone of the immune system are responsible to controlling microbial infection and have immunoregulatory properties, as well as a role in development of graft versus host disease (Louis and McGee, 1992).

Page 18, line 41, sentence **"Available blood tests have not been shown to provide useful diagnostic information, so no specific tests are currently recommended."** should be stricken and replaced **with "Because of concern over Natural Killer (NK-cell) counts which mav be adverselv affected bv exposure to silicone gel, the FDA requires the testing of NK-cell counts annually after imolantation with gel-filled devices for thirtv vears following implantation."**

Page 18, line 42. should read **"For this reason, FDA reauires the collection of serum (or plasma) samples from women pre-operatively and annually for 30 years after implantation of breast protheses. Samples must be stored frozen."**

Page 18, line 45, should read **"Patients must be monitored periodically and regularly for the occurrence of all complications and adverse events for a minimum of 30 years post-implantation (see Study Design/Statistical Issues section for a detailed description on sample size assessment)."**

Page 19, line 12, sentence should read **"All marketing claims (both explicit and implied) of equivalence or superiority to existing implants or therapies must be supported with statistically justified numbers of patients, clinically relevant endpoints, and with direct comparisons made to an appropriate control group. All advertising or promotional marketing must carry common adverse effects (i.e. high failure rates and local complications) just as all pharmaceutical or drug advertising must list common adverse effects and include the following 'Investigational device not FDA approved' until such time approval is obtained.".**

Page 19, line 3 1, should read **"A minimum duration of 10 years is recommended."**
The IOM report states that many satisfaction surveys are carried out immediately after surgery before the occurrence of untoward events.

Page 19, line 32, should read **"It is required that a measure of global satisfaction be assessed by an independent survey croup. This assesment must incorporate the effects of the following: the initial surgical procedure, adjunctive surgical and medical procedures, complications, and whether the expected benefits of the procedure and of the implants have been met.."**
The IOM report states "The committee believes that published reports of satisfaction are carried out by plastic surgeons or others associated with the surgery or care of women with implants. This arguably introduces a possible bias or distortion of patients' responses."

Page 19, line 38, should read **"The following information must be captured for any explanted implant."**

Page 20, line 9, should read **"The following must be reviewed by the physician or an assistant with the patient during the initial consultation:**

- **A copy of the package insert for the device the oatient is to have implanted along with a copy of the most recent FDA Breast Implant Information Booklet or FDA web site address if the oatient has access to a comouter.**
- **The patient must view a video, to be compiled as a co-ordinated effort between consumer advocates, plastic surgeon society, manufacturers, FDA, and**

breast cancer survivors to include pictures of successful outcomes along with pictures of local complications (i.e. Baker IV contracture. necrosis. infection. chronic inflammation. and disfigurement after removal for failed implants (equal time for both outcomes - positive and negative).

- **A copy of the informed consent. to be compiled bv the above co-ordinated group, to include a list of all chemicals (including common/generic names, all low molecular weight silicones. heaw metals, or other components) and their listed MSDS potential adverse effects. to be signed and returned at least 3 davs prior to surgery by the patient.**
- **Anv specific patient contraindications including genetic predisposition to connective tissue disease, relavant HLA typing, or previous allergic reactions.**

  Dr. Arthur Ericsson (1998) states "'There is a significant HLA-DR3 positivity in those with fibromyalgia associated with silicone-gel implants."
- **Any additional information related to the device such as lifetime renlacement and reimbursement policv information including estimated costs for renlacement cost not covered (i.e.. plastic surgeon's fees. operating room fees. etc.)**

At the time of surgery, the physician must complete an identification card and give to the patient specific device information (e.g. whether textured. smooth, saline-filled with a silicone shell, gel-filled, other fill, or double lumen), serial or lot number and other specific device information including manufacturer. Doctors who add antibiotics. steriods. etc. to breast implants must provide a notice in writing to the patient before surgery begins."

Our groups hear from many women who state they requested saline-filled implants but when they request their medical records, they find out they have gel-filled implants. Other women report when they request their medical records, different manufacturers implants were used during the same surgery (e.g. the right implant different manufacturer from the left implant).

Page **20, line 18,** should read **"Therefore, sponsors must advise against closed capsulotomy because it has been shown to potentially result in implant rupture. Additionally, sponsors must advise against the addition of substances into the filler (i.e. betadine, steriods, and antibiotics) other than those recommended because the substance may potentiate and/or accelerate delamination of the shell."**

Page 20, line 25, should read **"Therefore, these data must be collected on all reconstruction patients and on augmentation/reconstruction patients who develop breast cancer during the course of the study."**

Page 20, line 28, should read **"Otherwise, sponsors must be prepared to contact lost-to-follow-up patients at the end of the study and to demonstrate that the outcomes for these patients are the same as those for the patients who were compliant with follow-up."**

Page 20, line 34, should read **"Sponsors must provide at lease 3 years of premarket data for PMA filing for any materials."**

Page 20, line 36, should read **"Unless an adequate rationale is provided, silent rupture data for an alternative breast implant must be collected."**

Page 22, line 25, should read **"If the breast implant is being studied under an IDE, then the package labels, package insert, advertising or promotional material, and informed consent must include the following statement, 'CAUTION - Investigational Device. NOT FDA APPROVED. Limited by Federal (or United States) law to investigational use."**

Our groups hear from many women who state they did not understand that breast implants were not FDA approved or have never been proven safe or effective by the manufacturers.

Page 23, line 19, should read **"The directions must instruct caregivers to specifically question patients prior to surgery for any history of allergic reaction to any of the device materials or filling agents and for any genetic predisposition to autoimmune or connective tissue diseases."**

Page 23, line 24, should read **"Patient labeling must include the information needed to give prospective patients realistic expections of the benefits and risks of the device implantation. Such information must be written and formatted so as to be easily read and understood by most patients and must be provided at the initial consultation so that each patient has sufficient time to review the information and discuss it with her physician(s)."**

Page 23, line 30, should read **"The patient labeling must include, at minimum, the following information:**

Page 25, line 8, should read **"The majority of the data requested below must be reported for the separate patient cohorts of primary augmentation, primary reconstruction, and revision (i.e., the patient status/indication at study entry) as well as the total population."**

Page 25, line 11, should read **"Furthermore, the data must be provided on both a per patient and per device basis for most of the items below. Lastly. it is essential for the sponsor to provide all available data, including those data beyond the 3-year point.**

Page 25, line 15, should read **"A full patient accounting table must be provided on both a per patient and per device basis for each separate patient cohort and the total population.**

Page 25, line 16, should read **"The deaths and explantations must be reported cumulatively (i.e., continue adding across the time points instead of just reporting the number specific to one time point). This information must include the following information, at minimum:**

Page 26, line 5, should read **"It is our expectation that a minimum of 80% follow-up at the &year time point be provided at the time of PMA filing.**

We believe the above suggestions are reasonable in light of the serious health concerns regardiig the implantation of a non-life saving device that may remain over a long period of time in a patients body. May we remind the FDA the Nuremberg Code states "The voluntary consent of the human subject is absolutely essential. This means that the person involved should...be able to exercise free power of choice, without the intervention of any element of force, **fraud, deceit,** duress, **over-reaching,** or other ulterior form of constaint or coercion; and should have sufficient knowledge and comprehension of the element of the subject matter involved **as** to enable **him** to **make an understanding and enlightened decision."**

The IOM report recommended the following:

- "The development of a national model of informed consent for women undergoing breast implantation should be encouraged, and the continuing effectiveness of such a model should be monitored."
- "Ongoing surveillance of recipients of silicone breast implants should be carried out for representative groups of women, including long-term out comes and local complications."

We believe the suggestions made in this document will help in that development.

Respectfully,

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National non-profit network of organizations and concerned friends include the following:
Anne Stansell, United Silicone Survivors of the World (USSW)- New Mexico
Pamela Noonan-Saracini, Conneticutt Breast Cancer Survivor

Jama Russano, New York, Children Afflicted by Toxic Substances (CATS)
Kathy Keithley Johnston, Missouri, Toxic Discovery Network
Pamela Stott Kendall, Florida, author "Tom Illusions"
Martha Murdock, Texas, National Silicone Implant Foundation
Marti Jacobs, Arizona, Detox Network
Diana Payne-Reynolds & Sherry Henderson, Louisiana, Silicone Solutions Outreach
Jean Craig, Texas, Central Texas Silicone Implant Support, Inc.
Deana Cole, Missouri, Consumer Safety Advocate
Kim Hoffman, Missouri
Ilena Rosenthal, California, Humantics Foundation for Women, Breast Implants-Recovery & Discovery
Diane Griffith, USSW-Virginia
Lisa Hickey, Utah, Consumer Safety Advocate
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